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## REMARKS:

Claims 6, 7, 14, and 15 have been cancelled, claims 16-24 have been withdrawn as being directed to non-elected subject matter, and claims 25 and 26 have been added. Thus, claims 1-5, 8-13, and 25-26 are currently pending.

The Examiner rejected claims 3, 6, 8, 9, 11 and 14 under 35 U.S.C. 112, second paragraph, as being indefinite for using the term "substantially" (claims 3, 6, 11 and 14) or for containing a typographical error (claims 8 and 9). In response, the applicant has cancelled claims 6 and 14, has amended claims 3 and 11 to remove the term "substantially," and has corrected the typographical errors in claims 8 and 9 as shown in the amended claims above. Accordingly, all pending claims are now believed to be in compliance with 35 U.S.C. 112.

In addition, the Examiner rejected claims 1-15 as obvious under 35 U.S.C. 103 based on a combination of U.S. Patent No. 5,405,613 (Rowland) and U.S. Patent No. 5,294,606 (Hastings) (claims 1-4 and 6-7 ), Rowland in view of Hastings and U.S. Patent No. 6,024,960 (Kharazmi et al.) (claims 1-7 ), U.S. Patent No. 5,626,884 (Lockett) in view of Hastings (claims 1, 8-12 and 14-15), and Lockett and Hastings in view of Kharazmi et

al. (claims 1 and 8-15). As claims 6, 7 14, and 15 have been cancelled, the discussion below pertains to claims 1-5, 8-13 and 25-26 only.

Regarding claims 1-4, the Examiner states that, while neither Rowland nor Hastings teach the instant combination, it would have been obvious for one skilled in the art to combine the nutritional supplement of Rowland with that of Hastings because these references "teach that the ingredients comprising their nutritional supplements restore energy and provide beneficial health effects...." (Office Action, pages 4-5). Moreover, the Examiner contends that one of ordinary skill would have been motivated and one would have had a reasonable chance of success to add the composition taught by Rowland to the composition taught by Hastings due to the various health or immune system effects claimed by these inventors for each separate invention (Office Action, page 5). Finally, the Examiner relies on the proposition cited by *In re Sussman* (1943 C.D. 518) that there is "no invention in the combining old ingredients of known properties." (Office Action, page 5).

In response, the applicant respectfully submits that (1) neither Rowland nor Hastings explicitly teaches or suggests the

desirability of combining their nutritional supplement components to arrive at the present invention; (2) Rowland teaches away from the present invention by specifying bioflavonoids as only a "non-medicinal ingredient" in his composition; and (3) the level of unpredictability in the art is such that one of average skill would not have had been motivated to combine nor had a reasonable chance of success in arriving at the present invention for the stated purpose of supporting the immune system against mucosal infections (i.e., colds and flu).

Rowland discloses a number of vitamin/mineral compositions that essentially contain the substance "Shilajit." More particularly, what is considered inventive by Rowland is the specific combination of Shilajit with various vitamin or mineral preparations to enhance the "energetic properties" of such preparations (Summary of the Invention; col. 2, lines 40-48). Thus, Rowland teachings are limited to the combination of Shilajit with vitamins or minerals for the purpose of restoring "energy balance" or "bio-energetic fields" and for correcting "energy dysfunction" associated with various disease conditions (see lines 26-39, col. 5; emphasis added). In other words, Rowland only teaches the use of his supplement to correct

"unbalanced energy" resulting from sickness, not to support the immune system against mucosal infection.

Hastings teaches a sports "energy drink" composition that is claimed to enhance performance and to provide a better balance of electrolytes. While there is mention of Vitamin C and beta carotene to "facilitate immune function," nothing in Hastings teaches the use of his drink for the support of the immune system against mucosal infection. Hence, there is no suggestion to combine Hastings sports drink with Rowland's "energy balancing" tonic to achieve a dietary supplement useful for immune support against colds and flu.

Moreover, strictly speaking, Rowland cannot be said to suggest the combination of ingredients found in claim 1 of the present invention because he lists lemon bioflavonoids under the subheading "Non-Medicinal Ingredients" (see Table 4, col. 11). Thus, Rowland actually teaches away from the idea of adding lemon bioflavonoids to his compositions for medicinal purposes, such as support against mucosal infection.

In contrast, the present invention discloses a nutritional supplement that has nothing to do with Shilajit, "energy

balancing," or performance drinks, but that does essentially claim Vitamins A, C and D, zinc monomethionine, and a bioflavonoid (preferably lemon bioflavonoids) for the support of the immune system against mucosal infection. As disclosed by the applicant:

"The general health effects of the invention are supported by results obtained through actual use. For example, users have provided testimonial evidence indicating that they have experienced fewer or shorter mucosal infections as a result of adding the inventive supplement to their normal dietary intake" (Applicant's Specification, page 11).

Accordingly, without additional undue experimentation, there is no reason for one skilled in the art to look to Rowland or Hastings to arrive at the present invention.

Nor is there any suggestion or general knowledge by one skilled in the art that it would make it obvious to combine Rowland's and Hastings' teachings for the purpose of providing a nutritional supplement as claimed. Contrary to the Examiner's statement that the applicant is merely "combing old ingredients of known properties," the state of the nutrition and dietary supplement field is such that no one has been able to predict, *a priori*, which vitamin, mineral, or combination thereof will

posses immune-supportive characteristics, particularly against mucosal infections. Indeed, there is an abundance of prior art that states or suggests that one skilled in the art would not have a reasonable expectation of success in predicting or showing the efficacy of Vitamins A, C, or D, zinc monomethionine, or a bioflavonoid, either alone or in combination, against cold or flu frequency or duration.

Even scientists who are recognized authorities on alternative medicine and dietary supplements acknowledge the high degree of uncertainty when it comes to the health effects of supplements. For example, Dr. Kenneth R. Pelletier, Ph.D., M.D., Director of the Complementary and Alternative Medicine Program at the Stanford University School of Medicine, clearly states that "combining supplements with other over-the-counter supplements...is always complex and always potentially problematic, because quite honestly right now, this entire area is so new that we're only beginning to learn what these interactions are" (March 01, 2001 ABC News Chat Transcript, pages 1 and 4, attached as Exhibit 1).

Other references in the art provide truly conflicting accounts of how effective any one of the ingredients found in the present

invention are in terms of support against colds or flu. For example, "DiscoveryHealth.Com" states that "research on the effectiveness of large doses of vitamin C for the treatment of the common cold has produced conflicting results" (Attached as Exhibit 2). Furthermore, the same reference also states that "does of zinc above 100 mg may depress immunity" (emphasis added). Thus, one is left with the proposition that the combination of zinc and Vitamin C may actually be a waste of time and money or, perhaps, even worse for the immune system than doing nothing at all.

The Duke University School of Health website "Dukehealth.org" offers this blunt assessment of research on vitamin C and zinc: "There is no scientific evidence that taking megadoses of Vitamin C prevents colds or appreciably affects the duration of colds. Studies of zinc are inconclusive...." (Attached as Exhibit 3). Again, one is left with the proposition that if large doses of Vitamin C are thought to have no effect, it stands to reason that smaller doses are also of questionable efficacy. Furthermore, the value of zinc in fighting colds is questionable.



Moreover, a recent review of research on the subject of "zinc for the common cold" states that "Of the eight trials conducted since 1984 investigating the use of zinc in the treatment of the common cold, four have shown some benefit while the remainder have shown no benefit" (Cochrane Review Abstracts, Attached as Exhibit 4). Thus, those skilled in the art would consider the use of zinc in the treatment of colds to be an equivocal option at best.

Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991). In light of the many references in the art that challenge the efficacy of zinc or Vitamin C to support the immune system against colds and flu, it stands to reason that a cold-fighting composition or method providing both Vitamin C and zinc cannot be considered an obvious combination.

The Examiner also rejected claim 5 and 13 under 35 U.S.C. 103(a) as being obvious over Rowland and Hastings in view of Kharazmi et al. (claim 5) or over Locket and Hastings in view of Kharazmi

et al. (claim 13). The teachings of Kharazmi et al. are directed to "rose-hip formulations as **anti-inflammatory** natural medicine" (Title, emphasis added). By definition, a substance that is "anti-inflammatory" in character has a suppressive effect on the immune system (see Medterms.com: "Inflammation is defined as a type of nonspecific immune response"). Thus, it would be surprising (and certainly not obvious) to one skilled in the art to add rose hips to the composition of claim 1 for the purpose of supporting the immune system against mucosal infection in view of the immune suppressive effects taught by Kharazmi et al.

The Examiner further rejected claim 1 and claims 8-12 under 35 U.S.C. 103(a) as being obvious over Locket and Hastings. Again, the Examiner states that because each ingredient of the applicant's composition is well known in the art for their claimed purpose and can be found in the cited references, it would have been obvious to one skilled in the art to combine them to arrive at the present invention. However, there is no suggestion or motivation provided to combine Hastings' sports drink composition with Locket's sickle cell anemia treatment to provide a composition or method for immune support against mucosal infection.

The applicant also respectfully submits the fact that "optimization" or "substitution" of ingredients and/or dosages is not routine in this field, making applicant's invention particularly susceptible to the erroneous "obvious to try" analysis described in *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988). Indeed, given the high degree of uncertainty in the nutrition and dietary supplement areas, what would have been "obvious to try" in the present case would have been to vary all parameters or try each of numerous possible vitamin and mineral choices until one possibly arrived at a successful result. Such extensive experimentation would be necessary because the prior art gave either conflicting indications of which parameters were critical or conflicting direction as to which of many possible choices is likely to be successful. This degree of uncertainty in the art is true even in the area of "natural health or organic health" referred to by the Examiner (see Affidavit of Michelle Garcia, attached as Exhibit 5).

Hence, the applicant's claimed composition and method would not have been obvious over the prior art relied upon because no reference contains a suggestion to modify the prior art to produce the claimed invention and because there is ample

evidence suggesting that one skilled in the art had no reasonable expectation for success given the inconclusive state of research into the effects of the claimed vitamin, zinc monomethionine, and bioflavonoid combination on colds and flu.

It is worth noting that the applicant recognized the lack of direction in the prior art and proceeded to experiment until she found an inventive combination:

"However, the formulation and testing of a combination of zinc monomethionine and vitamins that are optimized to enhance absorption by the body and use by the immune functions has been elusive." Applicant's Specification, Page 3.

Thus, to further clarify the synergistic and surprising aspects of her invention, new claims 25 and 26 have been added. These claims explicitly limit the invention to a method for supporting a human immune system against mucosal infection by providing and administering a nutritional supplement including vitamin A, vitamin C, vitamin D, a bioflavonoid, and zinc monomethionine to a human before or during a mucosal infection. Nothing in the prior art explicitly or implicitly provides such a method.

In view of the reasons and amendments presented above, the applicant respectfully submits that Claims 1-5, 8-13, and 25-26 be considered for allowance.

Except for the enclosed petition fee for a two-month extension of time, no fee is believed to be due with this response. Should there be any unforeseen costs, please charge our Deposit Account No. 17-0055.

Respectfully submitted,



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## Alternative Medicine: What Works?

A Chat with Dr. Kenneth Pelletier

abc NEWS

March 1 — What are the most effective therapies in complementary and alternative medicine? How can they be used to prevent illness and enhance the quality of life? What is the scientific evidence of their safety and effectiveness?

Dr. Kenneth Pelletier, director of the Complementary and Alternative Medicine Program at the Stanford University School of Medicine, joined ABCNEWS.com today in an online chat, following his appearance on *Good Morning America*.

In his new book *The Best Alternative Medicine*, Pelletier rigorously evaluates the most common forms of alternative medicine, delivering research-based evidence about hundreds of individual treatments.

### FEATURED BOOK

*The Best Alternative  
Medicine: What Works?  
What Does Not*  
by Dr. Kenneth Pelletier



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Moderator at 11:42am ET

ABCNEWS' Charlie Gibson interviewed Dr. Pelletier this morning on *Good Morning America*. [Click here](#) to watch the interview.

Moderator at 11:58am ET

Welcome to ABCNEWS.com's live chat with Dr. Kenneth Pelletier, director of the Complementary and Alternative Medicine Program at the Stanford University School of Medicine. Dr. Pelletier, thanks for being here today.

Dr. Kenneth Pelletier at 11:58am ET

Thank you very much for the invitation.

Moderator at 12:03pm ET

Dr. Pelletier, before we begin, please outline what you consider to be the best alternative therapies.

Dr. Kenneth Pelletier at 12:05pm ET

The areas that are most commonly used, and these are perhaps 90% of what people use for alternative medicine, are the following: First, there's mind-body medicine, which includes stress management, meditation, biofeedback and the martial arts. These therapies actually have the largest body of scientific research showing they work for the largest number of conditions, for the most people.



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A second major area is the area of dietary supplements and herbs. Next is traditional Chinese medicine, Chinese herbals - somewhat different - and the usual herbs that we find largely from Europe and North America. Then there's acupuncture, homeopathy, chiropractic and spiritual healing. There are other areas such as naturopathy and ayurvedic, which is a dominant form of care in India, but these are not used as frequently in the United States.

Again, much to my surprise, there is the most research in the area of mind-body medicine — about 10 times the amount of good research showing that those approaches work, as opposed to any other area of alternative medicine.

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Steven from Schaumburg from *chi.ais.net* at 12:08pm ET  
What are the benefits and/or dangers of ginseng?

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**Dr. Kenneth Pelletier** at 12:09pm ET

Before I begin, a few words of caution: This is not medical or psychological advice. For any specific conditions you should talk with your doctor. Our discussion online cannot address specific conditions and is not a substitute for obtaining appropriate care. There's a lot I can offer in the way of specific information, but not for specific conditions.

Now to your question: Ginseng is an extremely expensive herbal — that's certainly one concern. It is very often claimed to be a tonic — an energy-enhancing tonic — and there is some evidence that it will work in that manner. But there are also claims that it will in fact act as an aphrodisiac, and there are no studies that indicate that it actually has that effect.

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**Moderator** at 12:10pm ET

Susan asks: What are your thoughts on the use of St. John's Wort to treat depression and are there other herbs that should or can be used to enhance its effectiveness?

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**Dr. Kenneth Pelletier** at 12:12pm ET

Since we're going down the herbal pathway, let me just include a couple of cautions which I think are important. There are several cautions to observe in the supplement and herbal area. One is that the ingredients stated on the bottle may or may not be in what you're consuming. Secondly, you need to purchase these from a nationally-recognized, reputable company. Thirdly, you should always tell your doctor or your therapist what you're taking because there are interactions between herbs and between herbs and drugs. And finally I would add that women who want to conceive, are pregnant, or are breast feeding should not be using herbals without contacting their doctor. They should probably not be using them at all.

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**Dr. Kenneth Pelletier** at 12:16pm ET

There is good research, predominately from Germany, that St. John's Wort does work for alleviating mild to moderate depression. In fact, just one figure that I remember, because it was so striking, is that in 1994 in Germany, they recorded 66 million daily doses of St. John's Wort for depression. This indicates that it is in widespread use and has had a long history of study.

Now, one major caution is that St. John's Wort can enhance the potency of prescribed antidepressants, and can produce an overdose-like effect. So again, you need to tell your doctor if you're taking both. Also, there was a study reported last week that indicated that St. John's Wort may diminish the potency of some other cholesterol-lowering medications, as well as some birth control pills.

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**Moderator** at 12:16pm ET

Many in our audience are asking about the benefits/dangers of Ginkgo Biloba. Please advise.

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**Dr. Kenneth Pelletier** at 12:20pm ET

Ginkgo Biloba actually comes from the world's longest living tree, and has been associated in Japan and China with long life, and it's one of the most frequently used herbals in China, Japan and Germany. There was a very good study in the *Journal of the American Medical Association* in 1997 which confirmed earlier findings that for people with early-onset symptoms of alzheimer's, Ginkgo improved their memory, depression and general intellectual skills, or delayed the progression.

But many people, perhaps most, are buying Ginkgo Biloba now on the sometimes-advertised belief that it will improve intelligence or intellectual functions with normal, young- to middle-aged individuals. At this point in time, there's no evidence that it has that effect.

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Eric from *proxy.aol.com* at 12:21pm ET

I am a recovering alcoholic. Are there any herbal supplements that have been shown to be effective in supporting recovery?

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**Dr. Kenneth Pelletier** at 12:22pm ET

Generally, in the area of substance abuse withdrawal, there is no single conventional or alternative intervention that works as a stand-alone, single therapy. Any effective intervention for addiction (and by addiction, I mean alcohol, cocaine and tobacco, those would be three of the most common addictions) would include a combination of psychological and group support, like AA and its offshoots, and certain conventional and alternative therapies.

For example, in the area of mind-body medicine, there is excellent research that shows various forms of meditation, stress-management, and biofeedback can eliminate or reduce the symptoms of withdrawal as part of a total program. The use of acupuncture has also been demonstrated to be effective with these substances, again as part of an overall program. And finally, especially with tobacco withdrawal, the use of both conventional and alternative pharmaceuticals or herbs to treat depression has been shown to ease withdrawal and to extend periods of abstinence.

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Mary at 12:25pm ET

Do the herbal medications for weight loss really work and are they safe?

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**Dr. Kenneth Pelletier** at 12:31pm ET

Weight loss is an extremely complex area. My short answer to your question is, no, for the following reasons: There are both over-the-counter and prescription appetite suppressants that do work for a short period of time. But all produce adverse effects if used beyond 30 to 60 days. So the real challenge of permanent weight loss is perhaps to use appetite suppressants in the short run, but only as part of a total program of changing your psychological orientation to food, reducing calories forever. Another component, increasing physical activity, is critical.

Every diet works — for a very short period of time. But without determination, a choice to make permanent, sustainable change, then a person is just looking for something from the outside that needs to come from the inside, which is his/her volition and choice.

One of the most common ingredients in over-the-counter appetite-suppressing weight loss herbs is Ephedra. There is no evidence that Ephedra as a stand-alone ingredient produces sustained weight loss. There is evidence that as a powerful stimulant, it can increase heart rate and blood pressure to dangerously high levels, and/or induce anxiety attacks.

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**Moderator** at 12:32pm ET

On *Good Morning America* you discussed the benefits of Saw Palmetto in the treatment of prostate problems.

**OxfordRO asks:** If taken, might this mask more serious symptoms such as prostate cancer?

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**Dr. Kenneth Pelletier** at 12:34pm ET

That's an excellent question. Saw Palmetto should only be taken after you've had a clear diagnosis of the fact that you have a benign, meaning noncancerous, enlargement of the prostate. If that is the case, and if you inform your doctor, then there is good evidence that Saw Palmetto can decrease the frequency of urination during the night. That is one of the main causes for disrupted sleep in middle-aged and older men. If the prostate enlargement is due to cancer or a malignancy, Saw Palmetto is not effective.

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**Moderator** at 12:35pm ET

Lois writes: I have heard taking herbs in a liquid/spray is more effective than a pill form. Is there any truth in that?

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**Dr. Kenneth Pelletier at 12:38pm ET**

We will see both prescription and over-the-counter supplements coming in many new forms. There will be inhalators, nasal sprays, patches, liquid form, as well as the more familiar capsules. For most herbs, the research has been conducted only on the oral, dried form, and less so on tinctures, or extracts of the herbal. There's almost no research on newer forms of delivery.

So when you think about using something, just simply remember that if it comes in a new delivery form, it is potentially more potent, because any substance distributed by nasal spray, sublingual - under the tongue - or in the form of a patch or an aerosol, bypasses the stomach and liver stages of breaking down that substance, and more of it is in effect delivered directly to the blood stream. So the initial loading dose could potentially be much higher than what is reported in the capsule-based research.

**Douglas Pratt from dialup.umn.edu at 12:38pm ET**

Is there any way to evaluate the quality of herbals? How does one find information about the reliability of various manufacturers?

**Dr. Kenneth Pelletier at 12:43pm ET**

In the vitamin supplement area, there is more reliable standardization, accuracy in labeling, and adequate disclosure of the content of most of those products. In the herbal area today, that is unfortunately not the case. But responsible herbal manufacturers are evolving toward such standardization and accurate disclosure, so consumers can make better decisions.

There have been several studies with several of the most commonly used herbs, such as Ginkgo, St. John's Wort, that we've already discussed, where they took products off the shelves and subjected them to what's called spectral analysis, and what they found was that upwards of as many as one third of the herbal preparations contained actually zero of the active ingredient, while others contained more than 100% of the labeled ingredient. And it varied from batch to batch, from the same producer.

So at the present time what I would suggest is to purchase any supplement or herbal product only from a nationally-recognized manufacturer, to avoid the lesser-known producers or a company which produces only a single one or two products. And thirdly, for the time being I would avoid products that are imported directly from Asia without United States inspection or oversight. Herbals from Europe generally meet or exceed United States standards.

**Amy from btebis.com at 12:43pm ET**

I've heard that combinations of vitamins E, D and aloe are helpful for skin conditions like psoriasis. Any dangers in combining vitamins and herbal remedies?

**Dr. Kenneth Pelletier at 12:46pm ET**

Combining supplements with other over-the-counter supplements, herbals or prescriptions is always complex and always potentially problematic, because quite honestly right now, this entire area is so new that we're only beginning to learn what these interactions are.

So ideally, it's best to use only one or two much more specific over-the-counter products, rather than trying to mix and guess what the effect is likely to be. Also, and I really underscore this, there are excellent herbalists, excellent naturopaths, homeopathic physicians, and conventional doctors, who are already using supplements and herbals and conventional medications. For a specific problem, that's the best place to go and get advice.

**Wayne from norwest.com at 12:46pm ET**

Why does there seem to be such a resistance from the United States medical community for the use of alternative therapies, herbal remedies, etc, when the remainder of the world's communities seem to support these time-tested methods of treating illness?

**Dr. Kenneth Pelletier at 12:51pm ET**

Actually, I've been very positively impressed at the degree of receptivity that there is to alternative medicine. There is skepticism, and I would include myself in that group that

wants to sort out what works from what does not.

I'll give you some examples of why I think there is some growing receptivity. Just last week the American Medical Association published a book under the title "Alternative Medicine," and there are articles in there that are very positive and confirm that certain alternative therapies are effective, while others are disproven and found to be ineffective, and that's the hallmark of good science.

Also, the National Institutes of Health created the National Center for Complementary and Alternative Medicine, which is funding approximately 50-60 million dollars a year in alternative-medicine research in medical schools including Columbia, University of Maryland, University of Arizona, Harvard and Stanford. Taken as a whole, I think this indicates a skeptical but serious and growing interest and acceptance of the possible and positive uses of a vast array of what we have called, to this point in time, alternative medicine.

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**Craig at 12:51pm ET**

Why do some people gravitate towards unproven herbal remedies when effective, proven, and accepted remedies are available? Is it the opportunity to self-prescribe that is the attraction? Could the label "Available By Prescription Only" be just another way of saying Too Expensive for Me? In other words, would the herbal market be flourishing if the more effective drugs were as readily available and as inexpensive? Is mainstream health care pricing themselves out of the medicine market?

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**Dr. Kenneth Pelletier at 12:57pm ET**

That is a very challenging question, and, to a certain degree, I think that you've made an accurate assessment, which is that people do perceive that many prescription drugs are too expensive, may have far too many side effects, and may not be readily accessible to themselves or to their doctors because of the limitations imposed by the drug formularies of most managed-care plans. And therefore, if a person believes, rightly or wrongly, that they can obtain an over-the-counter product that is less costly, maybe equally effective, and more readily accessible, then that certainly is an impetus for them to self-treat.

On the positive side, there are an increasing number of health insurance plans, and some managed care organizations, that are beginning to create networks of licensed, qualified clinicians, who can provide various forms of alternative medicine, including herbals, at a more reasonable price, that is more readily accessible. Perhaps the one country in the world where such a system is already in place and works extremely well is Germany, which is as sophisticated in terms of their scientific research and health care delivery as the United States. We seem to be evolving in a similar direction.

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**Moderator at 12:57pm ET**

Dr. Pelletier, thank you for your time today. Any final thoughts to share with our online audience?

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**Dr. Kenneth Pelletier at 12:59pm ET**

One of our studies in Stanford looked at whether people are opposed to conventional medicine and (do they) uncritically embrace alternative medicine — that's always the great fear. In this published study we found less than 3% of this national sample used alternative medicine only. So I am optimistic that we will see a time in the not too distant future, where the labels "alternative," "complementary," or "integrative," versus "conventional," just disappear and are replaced by an evidence-based health care that sorts out, based on good science, the most effective remedies.

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**Moderator at 1:05pm ET**

Dr. Pelletier is the author of the *The Best Alternative Medicine*. Thank you all for participating in this live event!



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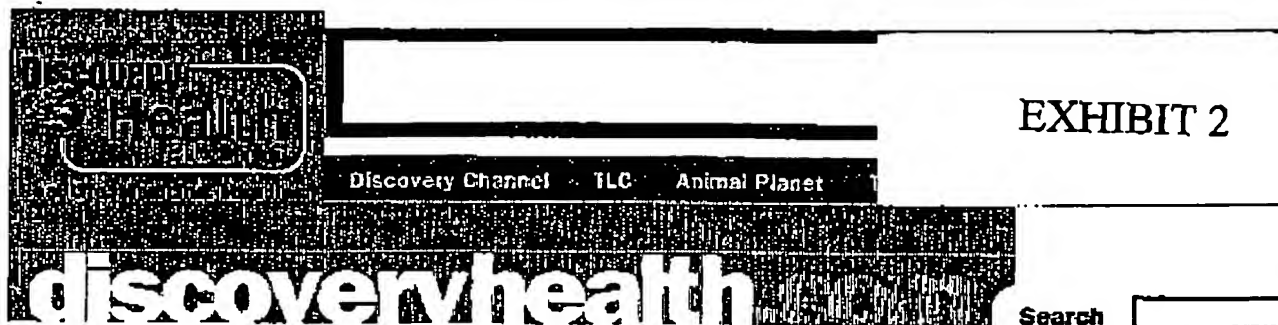
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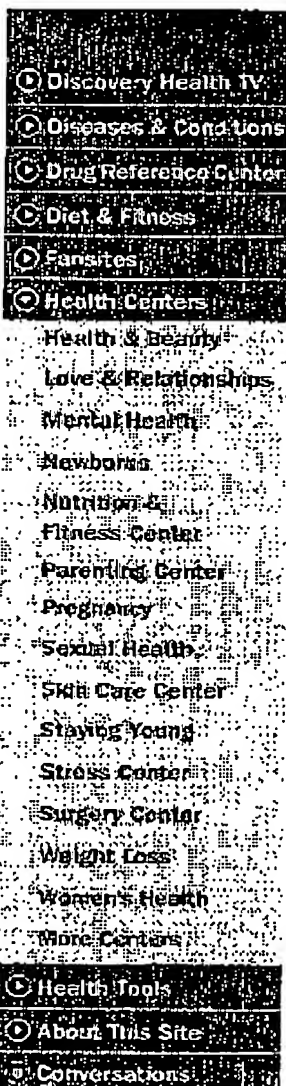
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## Diseases and Conditions Encyclopedia



## Diseases & Conditions

### vitamins, minerals, and colds

By Dr. Karen Wolfe, MBBS, MA

A cold is a viral infection that affects the upper airway including the nose, pharynx, throat, and lung airways.

#### What is the information for this topic?

Cold viruses are passed easily from one person to another. The best way for a person to avoid picking up cold germs is to wash his or her hands often and to keep hands away from the nose, eyes, and mouth. There is some evidence that both vitamin C and zinc can be effective for preventing or treating colds.

To stay healthy, the body needs vitamin C. Since this vitamin is water soluble, meaning it is not stored in the body, a person needs to eat foods rich in vitamin C daily or take a daily supplement. Research on the effectiveness of large doses of vitamin C for the treatment of the common cold has produced conflicting results. Most findings show that vitamin C has only a small effect on preventing a cold. But they do suggest that vitamin C given at the onset of a cold can reduce how long it lasts.

The best sources of vitamin C are • citrus fruits • strawberries • green and red peppers • tomatoes • potatoes • collard greens • broccoli • spinach

The recommended daily allowances, or RDAs, for vitamin C were recently increased. Levels were increased to provide maximum health benefits. Levels were raised to 75 mg per day for women and 90 mg per day for men. Smokers are advised to take an extra 35 mg daily. This is because smoking depletes the body of some vitamin C. Pregnant women and women who are breast-feeding need slightly more, too.

Large doses of vitamin C can cause stomach upset, diarrhea, or kidney stones. The upper level for vitamin C is 2,000 mg per day for adults. People should not routinely go above the set upper levels for vitamins and minerals. An upper level is not the recommended amount to take. It is the maximum amount of a vitamin or mineral that is likely to cause no health risks.

The body needs zinc for more than 200 enzyme activities. There are 2 possible ways this mineral helps prevent and treat the common cold: • It stops the growth of the cold virus. Certain viruses do not survive in a zinc-rich environment. This is the rationale behind zinc lozenges. • It stimulates the immune system. People whose diets lack zinc and people with low

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Discovery Health :: vitamins, minerals, and colds

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blood levels of zinc are more likely to catch a cold or another type of infection.

Best sources of zinc are • meat • mushrooms • oysters • eggs • brewer's yeast

The recommended daily allowance, or RDA, for zinc is 15 mg for males, aged 11 and older, and 12 mg for females, aged 11 and older. Pregnant women should get 15 mg. Women who are breast-feeding should get 19 mg the first six months and 16 mg the second six months.

Too much zinc might be as counterproductive to health as too little zinc. Doses of zinc above 100 mg may depress immunity. Zinc in excess of 150mg to 200 mg a day might interfere with copper absorption and could result in a secondary deficiency of this trace mineral. Zinc may also cause stomach upset.

Picture(s): DCI |

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Monday, December 22nd, 200

health briefs

## Avoiding the Common Cold

by William A. Christmas, MD, FACP

Associate clinical professor of community and family medicine and director of the Student Health Service

'Tis the season to be jolly -- but it's also the season for colds, which can make your holidays much less fun.

While there are things you can do to lessen your chances of getting sick, there are also many so-called remedies and preventive measures that just don't work. Here's some information to help you sort out fact and fiction--and boost your chances for a healthy holiday.

The truth about . . .

- **GETTING CHILLED.** Despite what your mother may have told you, going outside without a hat will not increase your chances of catching cold. In studies by Britain's Common Cold Unit during the 1940s, volunteers who were wet down and then exposed to cold air were no more likely to catch cold than control subjects in cozier conditions. Those results have been confirmed in many more studies since.
- **BEING IN CROWDS.** According to some experts, it can take up to several hundred hours of exposure to a cold virus to catch a cold--so you are more likely to catch cold from someone you spend a lot of time with, such as a family member, rather than through a chance encounter with strangers. Still, as cold virus particles can hang in the air for hours after someone coughs or sneezes, it is wise for the immunocompromised (including very young infants with immature immune systems) to avoid large gatherings or, if impossible, to wear surgical masks.
- **WASHING YOUR HANDS.** Most cold viruses are transmitted via hand-to-nose or hand-to-eye contact. For that reason, washing your hands frequently is the single most important thing you can do to prevent the spread of germs. The Centers for Disease Control recommends washing your hands with soap for 10 to 15 seconds (about the time it takes to sing "Happy Birthday to You"), as it is both the soap and the scrubbing action that help dislodge bacteria. However, it is not necessary to use . . .
- **ANTIBACTERIAL PRODUCTS.** Contrary to popular belief, these products do not kill the viruses that cause cold. Moreover, some researchers believe that overuse of such products could actually lead to new strains of resistant bacteria. For home use, regular soap is as effective, less expensive, and often less drying to the skin than antibacterial products. And remember--the scrubbing action is just as important, if not more important, than the cleaning agent you use.
- **DISINFECTING SURFACES.** Disinfectants such as Lysol and bleach solutions can kill viruses lurking on doorknobs, counters, and other surfaces in the home, but even the most vigilant cleaning is highly unlikely to kill everything--so be sure to wash your hands, and try to avoid touching your nose and eyes.
- **VITAMIN C AND ZINC.** There is no scientific evidence that taking megadoses of Vitamin C prevents colds or appreciably affects the duration of colds. In fact, overdosing can cause problems, such as severe diarrhea. Studies of zinc are inconclusive, but again, the mineral could cause problems in some people, so check with your doctor before taking it.
- **BEING CONSIDERATE.** If you already have a cold, try to avoid those who don't -- especially for the first three days, when you are most contagious. When you sneeze or cough, do so into a tissue, and then throw it away. And, finally -- keep washing those hands!

For more information about services offered by Duke, or for help in choosing a physician

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Duke Health Tip: Avoiding the Common Cold

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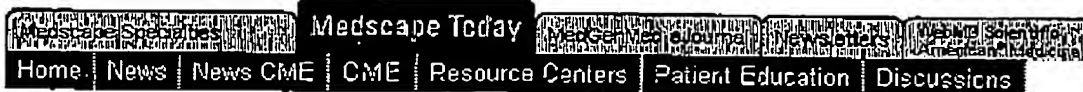
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## Zinc for the common cold

Updated: 04/01/2003

from Cochrane Review Abstracts

Posted 04/01/2003

Marshall I

A substantive amendment to this systematic review was last made on 15 February 1999. Cochrane reviews are regularly checked and updated if necessary.

**Background:** Of the eight trials conducted since 1984 investigating the use of zinc in the treatment of the common cold, four have shown some benefit while the remainder have shown no benefit. Treatment masking and reduced bioavailability of zinc from some formulations have been claimed to influence the results reported. This review was undertaken to assess the overall usefulness of zinc as a treatment for the common cold.

**Objectives:** Interest in zinc as a treatment for the common cold has grown following the recent publication of several controlled trials. The objective of this review was to assess the effects of zinc lozenges for cold symptoms.

**Search strategy:** A search was made of the Cochrane Controlled Trials Register, MEDLINE, EMBASE and reference lists of articles. Searches were run to the end of 1997.

**Selection criteria:** Randomised double blind placebo-controlled trials of zinc for acute upper respiratory tract infection or cold.

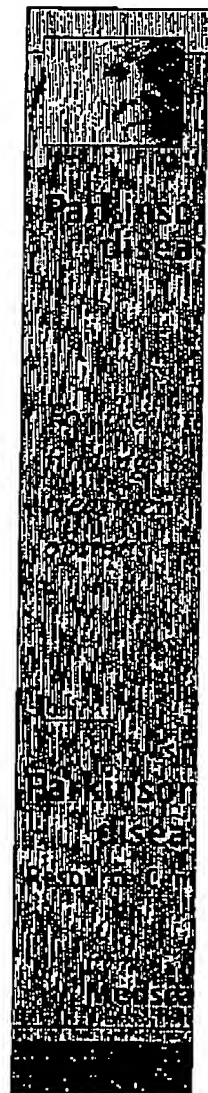
**Data collection and analysis:** Two reviewers independently extracted data and assessed trial quality.

**Main results:** Seven trials involving 754 cases were included. With the exception of one study, the methodological quality was rated as medium to high. For most outcome measures different summary estimates were used across the studies to describe the duration, incidence and severity of respiratory symptoms. This limited the ability to pool results. Results from two trials (04 - Mossad; 08 - Smith) suggested zinc lozenges reduced the severity and duration of cold symptoms. However, there was significant potential for bias, and further research is required to substantiate these findings. Overall, the results suggest that treatment with zinc lozenges did not reduce the duration of cold symptoms.

**Reviewers' conclusions:** Evidence of the effects of zinc lozenges for treating the common cold is inconclusive. Given the potential for treatment to produce side effects, the use of zinc lozenges to treat cold symptoms deserves further study.

[This abstract has been prepared centrally.]

**Citation:** Marshall I. Zinc for the common cold (Cochrane Review). In: *The Cochrane Library*, Issue 2 2003. Oxford: Update Software.





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**EXHIBIT 5****DECLARATION BY MICHELLE GARCIA,**

I, Michelle Garcia, hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that I have full knowledge and understanding of the fact that willful false statements and the like made herein are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that any such statements may jeopardize the validity of the above-referenced application or of any patent granted on it.

1. I have completed graduate studies in the field of nutrition, including specialized training in the medicinal use of vitamins and herbs in non-Western medical traditions.
2. I am currently employed as a chief vitamin buyer at Whole Foods Market in San Rafael, California, and my responsibilities involve research and development of new products in various fields, including nutrition and holistic health.
3. Prior to my current position, I worked as at Senior Health Educator at University of California San Francisco/Center for Aids Prevention Studies with responsibilities in the field of health education, particularly for immunocompromised individuals.
4. As a result of my educational and professional training and experience, I am very familiar with vitamins and minerals in general and vitamins A, C, D, zinc monomethionine, and bioflavonoids in particular, with their uses, and with the literature concerning efficacy in the prevention and/or treatment of the common cold and flu symptoms. Furthermore, I know and understand the literature concerning dosages and methods of administration of individual vitamins A, C, and D, as well as zinc monomethionine and bioflavonoids, to humans for various nutritional, preventive and therapeutic reasons.
5. I have read the present application, have read each of claims 1-15, and am familiar with the subject matter claimed as inventive in claims 1-15.
6. I have read the Office Action dated 07/23/2003 and issued by the Patent Office after examination of the application and, in particular, I understand the concerns expressed in Point 2 on pages 3-13.
7. I have also reviewed the references (Rowland, Hastings, Kharazmi, and Lockett) cited by the Patent Office as bases for rejecting the invention as obvious.
8. On the basis of my knowledge and experience in the art of nutrition and health education, it is my opinion that the composition described in the patent application for a combination of vitamins A, C, D, zinc monomethionine, and a bioflavonoid is not described in the referenced documents or, to my knowledge, anywhere in the literature on the subject.

9. It is further my opinion that the invention and the results derived from it are not readily apparent or obvious to a person skilled in the field, such as myself. That the combination of vitamins A, C, D, zinc monomethionine, and a bioflavonoid into one supplement is not obvious is clear from the fact that much debate has existed over the years about how efficacious any *one* of these components is with regard to immune system support. Moreover, to my knowledge, no one has ever suggested that this particular combination of substances or particular dosages would support the immune system with specific regard to cold and flu symptoms. Indeed, studies examining the effects of vitamin C and zinc on cold frequency and duration have produced conflicting results at best. Given this lack of consistent study outcomes, people in this field have been basing supplement composition and administration regimes simply on experience and empirical results.

10. Therefore, it is my opinion that the concerns expressed in the Patent Office's Office Action rejecting the application involve issues that would not be considered old or obvious by people working in the field.

11. I have no interest of any nature, past, present or future, financial or otherwise, in the invention and the patent application referenced above.

By: Michelle Garcia

Dated: 12/30/03

Printed or Typed Name: Michelle Garcia